K112077

MAR - 9 2012

510(k) summary

General Information

1 APPLICANT

Date: March 5th, 2012

Name: Corscience GmbH & Co. KG

Address: Henkestr. 91
D-91052 Erlangen
Germany

Contact person in the U.S.: **Patrik R. Karem**
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Contact person in Germany: **Karlheinz Trost**
Telephone: 01149 9131 977986 – 518
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E-Mail: trost@corscience.de

K. Trost

Signature: _____

2 TRADE NAME

HBIdb

3 COMMON NAME OR CLASSIFICATION NAME

Electroencephalograph

4 ESTABLISHMENT REGISTRATION NUMBER

3005488716

5 FACILITY ADDRESS

Corscience GmbH & Co. KG
Henkestr. 91
D-91052 Erlangen
Germany

6 DEVICE CLASSIFICATION

6.1 Classification

This is a class II device

6.2 Classification panel

PANEL: NEUROLOGY

Product Code: GWQ

6.3 Regulation Number

882.1400

7 PREDICATE DEVICES DESCRIPTIONS

7.1 Names

BRC Software Product
NeuroGuide Analysis System
Neurograph Evoked Potentials System
Neurometric Analysis System

7.2 Predicate Device Companies

BRC: BRC Operations Pty. Ltd, P.O. Box 737 Broadway, Sydney, NSW 2007 Australia
NeuroGuide: Applied Neurosciece Inc., 228 176th Terrace Drive, St. Petersburg, FL 33708
NeuroGraph: Thuris Corp., 110 Glenn Way # 6, San Carlos, CA 94070
Neurometric: NXLINK, Ltd., 1706 Gaillard Pl., Richland, WA 99352

7.3 Predicate Device 510(k)#

BRC: K050192
NeuroGuide: K041263
NeuroGraph: K010669
Neurometric: K974748

8 DEVICE DESCRIPTION

The Human Brain Index Software (HBIdb) product is a software program for the post-hoc statistical analysis and comparison with a reference data (the Human Brain Index Reference Database (HBIRD)) of the human electroencephalogram (EEG) including spontaneous oscillations of the human brain potentials and event-related potentials (ERPs). The EEG is recorded on a separate device under the standardized HBIdb conditions and is transferred to the HBIdb in EDF+ format for

- display
- spectral analysis and
- analysis of event-related potentials
- comparison of the gathered parameters against the Human Brain Index Reference Database (HBIRD), and
- compilation of a report.

Results of comparison of individual EEG/ERP parameters with the database are intended for use as an aid to diagnosis. No medication or treatment is applied based on this comparison alone. The results have to be considered only in conjunction with other clinical findings.

9 INDICATIONS FOR USE

The HBIdb product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG), utilizing evoked response potentials (ERP). The HBIdb product is intended for use on children and adults from age 7 to 80 years.

10 REQUIRED COMPONENTS

- HBIdb Software
- User manual
- SW dongle

Optional accessory

- None

11 SUMMARY TABLE OF COMPARISONS

	HBI software product To be cleared via this submission	**BRC software product** (K050192)	**NeuroGuide Analysis System** (K041263)	**NeuroGraph Evoked Potential System** (K010669)	**Neurometric Analysis System** (K974748)
Intended Use	The HBIdb product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroenceph alogram (EEG), utilizing evoked response potentials (ERP). The HBIdb product is intended for use on children and adults from age 7 to 80 years.	The BRC software product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electro-encephalogram (EEG), utilizing evoked response potentials (ERP).	The NeuroGuide Analysis System product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electro-encephalogra m (EEG).	The NeuroGraph Evoked Potential System (NeuroGraph EPS) is for use by qualified medical professionals and is intended to record and display electro-encephalogram (EEG) and evoked potential (EP) data in private practices, clinics or hospital environments to assist in the diagnosis and monitoring of central and peripheral nervous system disorders	The Neurometric Analysis System product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencep halogram (EEG).
EEG data comparison against normative database	Yes	Yes	Yes	Yes	Yes
ERP/EP data comparison against norm. database	Yes	Yes	No	Yes	No
Population	7 to 80 years	6 to 90 years	Birth to 82 y.	Unknown	6 to 90 years
Product code	GWQ	GWQ	GWQ	GWQ	GWQ
Classification	882.1400	882.1400	882.1400	882.1400	882.1400
ICA based artifact Correction	Yes	No	No	No	No
Decomposition of ERPs into independent components	Yes	No	No	No	No

All software products are to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electro-encephalogram (EEG) and compare the obtained EEG data against a normative database.
The age groups of all products are similar so that the software can be used on EEGs of subjects from childhood until old age.

12 SUMMARY OF DEVICE TESTING

The HBIdb product has been developed and validated according to the standard IEC 62304:2007. Software documentation and testing was provided in accordance with the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

For verification and validation of the product, all software functions were tested by means of specific EEG test files. Verification and validation were performed on an IBM compatible computer on the following operating systems: Windows XP 32 bit, Vista 32 bit, Windows 7 32 and 64 bit.
The security dongle was validated by means of a special utility supplied by the producer of the dongle.

The standard ISO 10993-1 does not apply to this product because it is a pure software product.

13 CONCLUSIONS

Based on the above, Corscience GmbH & Co. KG concludes, that the HBIdb product is substantially equivalent to legally marketed predicate software products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Corscience GmbH & Co. KG
c/o Mr. Karlheinz Trost
Quality Management and Regulatory Affairs
700-706 Seco Road
Monroeville, PA 15146

MAR - 9 2012

Re: K112077
Trade/Device Name: Human Brain Index Software (HBIdb)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLU
Dated: January 30, 2012
Received: January 31, 2012

Dear Mr. Trost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112077

Device Name: Human Brain Index Software (HBIdb)

Indications For Use:

The HBIdb product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG), utilizing evoked response potentials (ERP).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112077